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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,174	03/10/2004	Gerhard Siemeister	SCH-1815-C1	3503
23599 7590 03/17/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER				
HUGHES, ALICIA R				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
03/17/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/796,174

**Applicant(s)**

SIEMEISTER ET AL.

**Examiner**

ALICIA R. HUGHES

**Art Unit**

1614

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2 and 4-24 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 12-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-7, and 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims and Examination***

Claims 1-2, 4-7, and 9-11 are pending and the subject of this Office Action. Claims 8 and 12-24 are withdrawn from consideration, being drawn to a non-elected invention. See 37 C.F.R. 1.142 (b).

Applicants' arguments, filed on 10 December 2008, have been fully considered and are deemed to be persuasive regarding the previous rejection. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn.

Upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

### ***Restriction Requirement and Request for Rejoinder***

The Applicants have renewed their request that insofar as the Office has agreed to search the full scope of the genus claims, claims 14-18 should be examined at this time, also, because to do so would pose no serious burden to the Examiner. The Applicants are also requesting rejoinder of the process claims at this time.

The Applicants properly note that where product claims are found allowable, process claims that depend from or otherwise require all the limitations of the patentable product may be rejoined. The Office need not consider this request at present, as not claims have been held allowable at this time.

With regard to the renewed request that the Office now examine claims 14-18, Applicants' reason for the request is not found persuasive because the claims in the instant application are very broad and contemplate several distinct inventions, different compounds, for example, that are structurally and functionally different. As the examination of multiple inventions that would require an unduly burdensome search on the part of the examiner, restriction is proper. Thus, the requirement is still maintained in its finality.

***Claim Rejection – 35 U.S.C. §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-7 and 9-11 are rejected under 35 U.S.C. §103(a) as being obvious over Thorpe et al (U.S. Patent No. 6,703,020).<sup>1</sup>

The rejections germane to this portion of the present Office Action as set forth in the Office Actions filed on 02 November 2006, 20 September 2007, and 10 June 2008 are incorporated herein by reference.

Applicants still claim that their specification teaches that the modulation of two receptor systems unexpectedly results in superior pharmacological effects and that insofar as Thorpe et al is silent with respect to the combination recited in Applicants' claim 1 - which has been amended now to include the limitation "wherein said compound I and said compound II are not identical to one another" - the instant invention is unobvious.

These arguments have been thoroughly considered. With regard to the amended language, the claims still read on the prior art of record, because Thorpe et al disclose treatment by the administration of certain compounds and mixtures thereof, with the operative word being mixtures (Col. 1, lines 16-26 and Col. 3, lines 34-42). It necessarily follows that mixtures or combinations thereof means heterogeneity rather than homogeneity. Thus, the compounds are not necessarily the same. With regard to the Applicants' other arguments, for the reasons previously made of record, they are not deemed to be persuasive. The examples cited by Applicants do not support a synergistic effect inasmuch as Examiner interprets them to be demonstrative of an additive one. In light of the foregoing, the rejection is therefore maintained.

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<sup>1</sup> Cited on previous PTO-892.

### **Conclusion**

No claims are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/  
Examiner, Art Unit 1614

/Raymond J Henley III/  
Primary Examiner, Art Unit 1614